510(k) Summary
X-Suit NIR® Biliary Metallic Stent

JAN - 9 2009

Submitter:

Medinol Ltd
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Contact Person:

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Date Prepared: July 7, 2008

Trade Name: X-Suit NIR® Biliary Metallic Stent

Regulation Name: Biliary catheter and accessories

Classification Number: 21 CFR 876.5010

Product Code: 78 FGE

Predicate Devices:

Cook Incorporated Zilver Biliary Stent – K010242

Wilson – Cook Medical Inc. Zilver Biliary Stent – K020788

Bard Luminexx Endoscopic Biliary Stent – K031186

Boston Scientific Wallstent Biliary Endoprostheses - K925406, K961262, K964119, K000308, K012752

Device Description:

The X-Suit NIR® Biliary Metallic Stent is designed to maintain the patency of biliary ducts obstructed by malignant biliary strictures. The device is comprised of a self-expanding stent, which is pre-loaded on a delivery system. The stent is available in 8 and 10mm labeled diameters, and 40 – 100mm labeled lengths.

Intended Use:

The X-Suit NIR® Biliary Metallic Stent has been designed for palliation of malignant strictures in the biliary tree.

Functional Testing:

Laboratory testing was performed. In some instances, legally marketed biliary stent systems were tested as control devices for the purpose of comparison with the X-Suit NIR® Biliary Metallic Stent device.

In addition, test results and information were also provided in accordance with the following:

- Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents February 5, 1998;
- International standards Organization's ISO-10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing;
- FDA's Updated 510(k) Sterility Review Guidance (K90-1); Final Guidance for Industry and FDA, August 30, 2002;
- ASTM F 2063-05, Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants;
- ASTM F 560-05, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)
- MRI Standards, ASTM F2503-05, ASTM F2213 – 06, ASTM F2052-06e1, ASTM F2182-02a, ASTM F2119-07.

Summary of Substantial Equivalence:

The design, material, components, fundamental technology and intended use of the X-Suit NIR® Biliary Metallic Stent device are substantially equivalent to those of the predicate devices cited above. Substantial equivalence is based upon descriptive characteristics of the various devices and upon the safety and performance testing completed. The information provided demonstrated that the proposed device meets the same performance requirements and is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2009

Medinol, Ltd.
c/o Mr. Leo L. Basta
Partner
Boston Biomedical Associates, LLC
386 West Main Street, Suite 7
NORTHBORO MA 01532

Re: K081956
Device Name: X-Suit NIR® Biliary Metallic Stent
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: December 18, 2008
Received: December 22, 2008

Dear Mr. Basta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081956

Device Name: X-Suit NIR® Biliary Metallic Stent

Indications For Use: X-Suit NIR® Biliary Metallic Stent is indicated for the palliation of malignant strictures in the biliary tree.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K081956